



DT03 R PCT/PTO 28 DEC 2004

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/509,252 ✓  
Filing Date: September 28, 2004  
Applicant(s): Shunichi KURODA et al.  
Group Art Unit: Unknown  
Examiner: Unknown  
Title: DRUGS FOR TREATING HEPATIC DISEASES WITH THE USE  
OF HOLLOW PROTEIN NANOPARTICLES  
Attorney Docket: 12480-000069/US

U.S. Patent and Trademark Office  
220 20<sup>th</sup> Street S.  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

December 28, 2004

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

**I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information submitted for consideration by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

**II. COPIES**

A. ☐ Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cited pending U.S. application, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☒ Because the present application was/is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

D. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. Since the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☐ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:
2. ☐ English translations are provided for:
3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☐ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. ☒ 37 C.F.R. § 1.97(b): (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. ☒ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). **No fee or certification is required.**

3. ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☐ 37 C.F.R. § 1.97(c): (check only one box)

☐ before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ 37 C.F.R. § 1.97(d):

☐ after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

- A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F. R. 1.704(d) below in section VII, if applicable; or
- B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).
- C. ☐ Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

- A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.
- B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

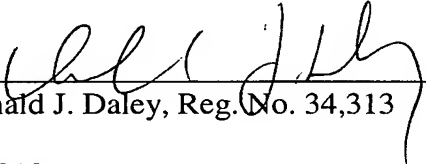
The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

HARNESS, DICKY & PIERCE, P.L.C.

By   
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DJD/bof

Enclosures: ☒ Form PTO-1449(s)  
☒ Documents  
☐ Foreign Search Report  
☐ Fee  
☐ Other:

Rec'd PTO

28 DEC 2004

#5  
Sheet 1 of 1

Form PTO-1449

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

(Use several sheets if necessary)

ATTY DOCKET NO.  
12480-000069/USAPPLICATION NO.  
10/509,252APPLICANTS  
Shunichi KURODA et al.CONF. NO.  
UnknownFILING DATE  
September 28, 2004GROUP  
Unknown**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	2003/0092069 A1	5/15/2003	Kuroda et al.			

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
						YES	NO

**OTHER DOCUMENTS** (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

		Hiromitsu JINNO et al., "Epidermal Growth Factor Receptor-Dependent Cytotoxicity for Human Squamous Carcinoma Cell Lines of a Conjugate Composed of Human EGF and RNase 1", Life Sciences, Vol. 58, No. 21, pp. 1901-1908 (1996).
		Goretti MALLORQUÍ-FERNANDEZ et al., "Three-dimensional Crystal Structure of Human Eosinophil Cationic Protein (RNase 3) at 1.75 Å Resolution", J. Mol. Bio., 300, pp. 1297-1307 (2000).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DJD/bof